IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

MARY ANN WARD,

Plaintiff,

v.

Case No.: 2:20-cv-00334
Judge:

LiNA MEDICAL USA, INC. d/b/a LiNA MEDICAL,
LiNA MEDICAL ApS d/b/a LiNA MEDICAL,
LiNA MEDICAL POLSKA SP. Z.O.O. d/b/a LiNA MEDICAL,
KEBOMED, A.G. d/b/a LiNA MEDICAL,
THE UNITED STATES OF AMERICA,
RALEIGH GENERAL HOSPITAL, LLC, and
LIFEPOINT HEALTH,

Defendants.

COMPLAINT

Now comes Plaintiff, Mary Ann Ward, by counsel, and states as follows:

I. Parties, Jurisdiction & Venue

1. Plaintiff Mary Ann Ward is a resident of the Southern District of West Virginia and sought medical treatment therein.

2. One of the claims herein is brought against the United States pursuant to the Federal Tort Claims Act (28 U.S.C. §2671, et seq.) and 28 U.S.C. §§1346(b)(1), for money damages as compensation for personal injuries that were caused by the negligent and wrongful acts and omissions of employees of the United States Government while acting within the scope of their offices and employment, under circumstances where the United States, if a private person, would be liable to the Plaintiffs in accordance with the laws of the State of West Virginia.

3. A claim is being brought against Defendant Raleigh General Hospital, LLC d/b/a Raleigh General Hospital which is a West Virginia citizen that is headquartered in and otherwise conducts business in the Southern District of West Virginia. Defendant LifePoint Health is the foreign entity that owns Raleigh General Hospital.

4. Defendant LiNA Medical USA, Inc. d/b/a LiNA Medical is a Georgia corporation with offices in Norcross, Georgia. At all relevant times herein, LiNA Medical USA, Inc. was engaged in the business of manufacturing, selling, supplying, distributing, marketing and/or designing gynecological surgical products.

5. Defendants LiNA Medical ApS d/b/a LiNA Medical; LiNA Medical Polska SP. Z.O.O. d/b/a LiNA Medical; and Kemomed, AG d/b/a LiNA Medical are all foreign corporations. This family of foreign LiNA Medical companies were at times relevant herein engaged in the business of manufacturing, selling, supplying, distributing, marketing and/or designing gynecological surgical products.

6. Venue is proper in that all, or a substantial part of the acts and omissions forming the basis of these claims occurred in the Southern District of West Virginia.

7. Plaintiff has fully complied with the provisions of 28 U.S.C. §2675 of the Federal Tort Claims Act.

8. Plaintiff has fully complied with prerequisites of the West Virginia Medical Professional Liability Act ("MPLA") to the extent it may apply in some limited instances in this case.

II. Procedural History

9. On September 13, 2018, Plaintiff sent the original Notice of Claim to Dr. Juddson Lindley ("the doctor") at AccessHealth Associates, which explained the basis for her claim.

10. In 2018, counsel for Plaintiff was notified by the United States government that the doctor was employed by a federal facility and essentially that any claim would have to be brought pursuant to the Federal Tort Claims Act.

11. Plaintiff provided further documentation to the United States in support of her claim per its request.

12. On March 4, 2020, the United States sent out correspondence to counsel for Plaintiff indicating it was denying the claim but did not explain the basis for its denial.

13. On March 19, 2020, Plaintiff sent an Amended Notice of Claim with a Screening Certificate of Merit to the doctor and to counsel for the United States.

14. On April 8, 2020, Plaintiff sent a Notice of Claim and Screening Certificate of Merit to Raleigh General Hospital, along with a contemporaneous voluntary Notice of Claim to LiNA Medical.

III. Facts Relating to Morcellation Generally

15. Hysterectomies are the second most common surgery after birth by cesarean delivery.

16. In conventional non-power morcellator hysterectomies, the woman's entire uterus is removed essentially intact through an incision.

17. Power morcellators are electric devices with fast-spinning blades that allow surgeons to cut up large pieces of tissue like the uterus or fibroids into smaller ones and remove them through small incisions in the abdomen during laparoscopic surgery. The morcellator's

spinning blades shred the tissue masses at high velocity and can disperse cellular particles from the shredded tissues throughout the abdomen during surgery. These morcellators began to hit the market in 1995.

18. Early on in their use, the medical community began to highlight that laparoscopic power morcellators could cause occult malignant tissue fragments to be disseminated and implanted throughout the body, thereby spreading previously undetected cancer. *See, e.g.*, Rivard, *et al., New challenges in detecting, grading, and staging endometrial cancer after uterine morcellation*, 19 J. MINIM. INVAS. GYNECOL. 313-16 (1997); 177 AM. J. OBSTET. GYNECOL. 478, 478-79 (1997); Francis Hutchens and Elizabeth Reinoehl, *Retained Myoma after Laparoscopic Supracervical Hysterectomy with Morcellation*, 5 J.AM. OBSTET. GYNECOL. LAPAROSC. 293, 293-95 (1998); LaCoursiere, *et al.*, *Retained Fragments after total laparoscopic hysterectomy*, 12 J. MINIM. INVAS. GYNECOL. 67-69 (2005); Larrain, *et al.*, *Iatrogenic parasitic myomas: unusual late complications of laparoscopic morcellation procedures*, 17 J. MINIM. INVAS. GYNECOL. 719-724 (2010); Ramm, *et al., Utility of preop endometrial assessment asymptomatic women undergoing hysterectomy*, 23 INT. UROL. GYNECOL. J. 913-17 (2012).

19. In 2009, the American College of Obstetricians and Gynecologists (ACOG) recommended vaginal hysterectomy as the best technique with better outcomes and fewer complications than laparoscopic or abdominal hysterectomy.

20. In 2013, Dr. Amy Reed and her husband, Dr. Hooman Norchasm, launched a campaign against the use of power morcellators.

21. In December 2013, *The New York Times* published an article about Reed's case, prompting discussions about morcellator risks and benefits.

22. Also, in December 2013, the Society of Gynecologic Oncology (SGO) issued a statement that health care providers should inform patients of risks and should not morcellate tissue in patients with possible cancer. The SGO recommended that medical providers conduct pre-operative screening evaluations to discover the existence of uterine or cervical malignancy in patients. *SGO Position Statement: Morcellation*, SOCIETY OF GYNECOLOGIC ONCOLOGY (December 2013), https://www.sgo.org/newsroom/position-statements-2/morcellation/.

24. In January 2014, the American Association of Gynecologic Laparoscopists (AAGL) created a task force to examine the risks of power morcellators.

25. In February 2014, Temple University Hospital required morcellation to be performed in a containment bag to catch tissue. Fibroids bigger than 7 inches must be removed whole, through a large incision.

26. Also in February 2014, the Lancet called for urgent attention to the risk of morcellation and called the risk of spreading disease unacceptable. *Patient Safety must be a priority in all aspects of care*, THE LANCET ONCOLOGY, Vol. 15 (2) (February 1, 2014).

27. In March 2014, Brigham and Women's Hospital required doctors to morcellate tissue within a bag.

28. Controversy exploded over laparoscopic power morcellators in April 2014 when the FDA released a warning that, for a subset of women with undiagnosed uterine cancer, the morcellation would shred cancerous tissue and spread it in the abdomen worsening the cancer. The FDA warned that 1 in 350 women who undergo morcellation for hysterectomy or

myomectomy may have undiagnosed uterine cancer. The power morcellator may shred cancerous tissue and spread it in the abdominal cavity, worsening the cancer. This means a tumor may be "upstaged" from stage 1 to 4 after morcellation, which makes the cancer difficult to treat and decreases the chances of long-term survival.

29. The FDA ultimately discouraged the use of laparoscopic power morcellation during hysterectomy or myomectomy for uterine fibroids. *Laparoscopic Uterine Power Morcellation in Hysterectomy and Myomectomy: FDA Safety Communication*, Silver Spring: U.S. Food and Drug Administration (April 17, 2014).

30. After the FDA warning in 2014, Johnson & Johnson, the then worldwide leader in manufacturing power morcellators, pulled its power morcellators off of the market.

31. The 2014 FDA warning received attention in the medical community.

32. In 2017, the FDA re-affirmed its 2014 guidance with respect to power morcellators.

33. It is clear that morcellation spreads and upstages uterine cancer.

IV. Facts Relating to Treatment of Mary Ann Ward

34. As set forth in the Notice of Claim and Amended Notice of Claim, during the treatment of Mary Ann Ward in May of 2018 by Dr. Lindley of Access Health Associates in Beckley, Raleigh County, West Virginia, the decision was made to go through with a hysterectomy due to the worsening of a bowel protrusion.

35. The doctor made the decision to morcellate the uterus but did not discuss the morcellation procedure with Plaintiff and its risks.

36. The Defendant doctor did not do an endometrial biopsy on Plaintiff prior to the morcellation procedure.

37. Had such a biopsy been done, it would have revealed the cancer, and Dr. Lindley acknowledged he would not have performed the morcellation procedure had he known about the cancer.

38. On May 16, 2018, the doctor morcellated the Plaintiff's uterus.

39. Following the procedure that day, the doctor remarked to the Plaintiff that her uterus was abnormal in size.

40. On May 22, 2018, a pathology report revealed that Plaintiff had cancer, and the doctor spoke with Plaintiff around that time to notify her that she had cancer.

41. As indicated above in the discussion on the FDA's warning, the morcellation spread the cancer cells in Mrs. Ward's case.

42. Mary Ward's granddaughter, who attended the doctor's visit with her, happened to be recording the conversation between Mary Ward and the doctor in June of 2018. During this recording, the doctor admitted the following:

(a) During a conversation with Mary Ward, he admitted that he "screwed up"; "dropped the ball" and that this was a "swing and a miss." He admitted that he would be mad, too, if he were in Mrs. Ward's shoes. To his credit, he accepted responsibility for his actions.

(b) He admitted that he did not discuss the risks of morcellation, or even mention "morcellation" at all, with Mrs. Ward.

(c) He admitted that he should have done a biopsy before morcellating.

(d) He admitted that had he done a pre-operative biopsy and known she had cancer, he would not have done the morcellation surgery.

(e) He admitted that had her uterus been removed without morcellation, Mrs. Ward would not have had to undergo the lymph node dissection, the chemotherapy and other "additional crap," as he put it.

A copy of the recording was provided to the parties.

43. Dr. Lindley referred Plaintiff to WVU, where she was told the situation was "treatable, not curable" and was directed to start chemotherapy immediately.

44. Plaintiff's attempts to resolve the matter have been unsuccessful as Defendants have not offered any remuneration to compensate Mrs. Ward.

V. The Xcise Laparoscopic Power Morcellator and its Manufacturer, LiNA Medical

45. Long before Plaintiff underwent surgery in 2018, Defendants LiNA Medical USA, Inc.; LiNA Medical ApS; LiNA Medical Polska SP. Z.O.O.; and Kebomed, AG, all doing business as LiNA Medical (collectively "the LiNA Medical Defendants"), knew or should have known that their LiNA Xcise model morcellator could cause malignant tissue fragments to be dispersed and implanted in the body, which would upstage any cancer present and substantially decrease a woman's chance of survival.

46. The LiNA Medical Defendants failed to adequately respond to numerous published studies describing the cancer-spreading risks associated with power morcellators, and failed to design their Xcise model morcellator in a manner to minimize this life-threatening risk.

47. Knowing that their power morcellators had the potential to spread and worsen a woman's occult cancer, the LiNA Medical Defendants should have designed, marketed, and sold

their LiNA Xcise model morcellator with a containment bag or other device designed to prevent the risk of disseminating cancerous tissue.

48. The American College of Obstetrics and Gynecology (ACOG), the Society of Gynecologic Oncology (SGO), and the American Association of Gynecologist Laparoscopists (AAGL) all suggest containment bags as potential solutions to prevent dissemination of cancerous tissue during morcellation. Winner, Brooke, and Scott Biest. *Uterine Morcellation: Fact and Fiction Surrounding the Recent Controversy*. MISSOURI MEDICINE Vol. 114 (3) 176-180 (2017).

49. The surgical containment bag system and other preventative designs have been available since the early 1990s, long before the Xcise model morcellator was brought to market.

50. Because of the LiNA Medical Defendants' failure to adequately warn surgeons and hospitals of the risk of morcellator use as well as the LiNA Medical Defendants' failure to adequately recommend, require, or design a system that would prevent the dissemination of occult cancer, Plaintiff suffered avoidable bodily injury that may also significantly decrease her life expectancy.

VI. Claims

(COUNT I - VIOLATION OF FEDERAL TORT CLAIMS ACT)

51. Plaintiff incorporates by reference herein all allegations set forth herein.

52. Defendant USA owed Plaintiff a duty of care when she came to the medical facility to be treated.

53. The accepted standard of care for a patient in Mrs. Ward's condition required the doctor to do an endometrial biopsy and discuss the risk of morcellation, as the doctor acknowledged to the patient in the recorded interaction.

54. Defendant USA's breaches of the standard of care caused Plaintiff to suffer damages, including but not limited to her having to undergo chemotherapy and lymph node dissection, *etc.*

(COUNT II - NEGLIGENCE AGAINST RALEIGH GENERAL HOSPITAL, LLC AND LIFEPOINT HEALTH)

55. Plaintiff incorporates by reference herein all allegations set forth above.

56. Defendants Raleigh General Hospital, LLC and LifePoint Health (together d/b/a "Raleigh General Hospital" or "Defendant hospital") owed Plaintiff a duty of care.

57. Defendants Raleigh General Hospital, LLC and LifePoint Health knew or should have known about the problems and substantial risks with the morcellator and the way it spreads and upstages cancer well before Mrs. Ward's surgery.

58. Defendant hospital owned the power morcellator used in Mrs. Ward's surgery.

59. Following the FDA's actions in 2014, many hospitals banned laparoscopic power morcellation outright, and others created requirements for power morcellation such as pre-surgical endometrial biopsies and new consent processes.

60. Yet, Raleigh General Hospital and LifePoint Health failed to take any of these measures as well as other appropriate and reasonable measures to ensure that Mrs. Ward's cancer would not spread through morcellation and failed to warn Mrs. Ward and the general public at large of said problems and dangerous risks to ensure that Mrs. Ward was making an informed decision in proceeding with the morcellation.

61. The accepted standard of care required the Defendant hospital to either ban morcellation or equip the morcellator with an appropriate failsafe to ensure that these machines could not be used to spread and upstage cancer.

62. Further, the accepted standard of care required the Defendant hospital to ensure that all morcellation patients understand the substantial and dangerous risks that they were undertaking by agreeing to the morcellation procedure.

63. As aforesaid, these breaches of the standard of care by the Defendant hospital proximately caused Mrs. Ward to suffer damages, including, *inter alia*, the undergoing of chemotherapy, which she would not have otherwise had to do.

(COUNT III - STRICT PRODUCTS LIABILITY AGAINST LINA MEDICAL DEFENDANTS - FAILURE TO WARN)

64. Plaintiff incorporates by reference herein all allegations set forth above.

65. The morcellator used at Raleigh General Hospital by Dr. Lindley was the Xcise model morcellator manufactured by LiNA Medical.

66. At all times relevant to the suit, the LiNA Medical Defendants knew of the Xcise model morcellator's dangerous propensities, or such dangers was reasonably known to the LiNA Medical Defendants, through research and/or testing by known methods, at the time they marketed, distributed, supplied, and sold the product.

67. The Xcise model morcellator reached Plaintiff without substantial change and was used as directed.

68. The Xcise model morcellator was defective and unreasonably dangerous in that the labeling was insufficient to adequately warn medical providers and patients of the significant

risks of disseminating occult cancerous cells and the resulting likelihood of upstaging patients' cancer.

69. The LiNA Medical Defendants failed to take appropriate and reasonable measures to ensure that Mrs. Ward's cancer would not spread through morcellation and failed to warn Mrs. Ward and the general public at large of said problems and dangerous risks to ensure that Mrs. Ward was making an informed decision in proceeding with morcellation.

70. The LiNA Medical Defendants failed to adequately warn and inform medical providers and patients of the following risks associated with the Xcise morcellator, among other deficiencies:

(a) Failing to disclose and/or understating the risk of disseminating cancerous tissue throughout the patient's abdomen;

(b) Failing to adequately advise physicians to conduct pre-operative screenings to detect the presence of uterine cancer prior to morcellation procedures;

(c) Failing to disclose the actual rates at which laparoscopic power morcellators disseminate and/or upstage cancerous and non-cancerous fibroid tumors; and

(d) Failing to disclose the possibility of additional treatment and procedures, and/or the need for additional surgery, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of the increased risk of these injuries and side effects over alternative forms of treatment for uterine fibroid removal.

71. As a direct and proximate result of the foregoing actions and omissions of the LiNA Medical Defendants, Plaintiff suffered damages.

(COUNT IV - STRICT PRODUCTS LIABILITY AGAINST LINA MEDICAL DEFENDANTS – DESIGN DEFECT)

72. Plaintiff incorporates by reference herein all allegations set forth above.

73. The LiNA Medical Defendants placed the Xcise model morcellator into the stream of commerce and reached the Plaintiff without any alterations or changes.

74. The Xcise model morcellator was defective in design in at least the following respects:

(a) When it left the hands of the LiNA Medical Defendants, the Xcise model morcellator was unreasonably dangerous to an extent beyond which could have reasonably contemplated;

(b) Any benefit of the Xcise model morcellator was outweighed by the severe and undisclosed risks of its use when used as the LiNA Medical Defendants intended:

(c) There were safer alternative designs that did not carry the same risks as the Xcise model morcellator that were known to the LiNA Medical Defendants, such as the traditional hysterectomy and the bag containment systems referenced herein;

(d) The Xcise model morcellator utilized in Plaintiff's hysterectomy was defective at the time it was distributed by the LiNA Medical Defendants or left its control.

75. The LiNA Medical Defendants knew or should have known that physicians and other medical providers would use and hospitals would promote and allow the use of the Xcise model morcellator as though it were a safe and effective device for uterine surgery, despite its lack of efficacy, potential for upstaging cancer and other life-threatening side effects.

76. The accepted standard of care required the manufacturer to recall the morcellators or equip the morcellators with an appropriate failsafe to ensure that the machines could not be used to disseminate and upstage cancer.

77. As a direct and proximate result of the defective and unreasonably dangerous condition of the Xcise model morcellator, Plaintiff suffered damages.

(COUNT V - BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS AGAINST LINA MEDICAL DEFENDANTS)

78. Plaintiff incorporates by reference herein all allegations set forth above.

79. The LiNA Medical Defendants are merchants with respect to the Xcise model power morcellator used in Plaintiff's hysterectomy.

80. The Xcise model power morcellator designed and manufactured by the LiNA Medical Defendants was sold with implied warranties of merchantability and fitness, *i.e.*, Defendants impliedly warranted that the subject morcellator was fit for the ordinary purpose for which it was sold.

81. Plaintiff reasonably relied on the LiNA Medical Defendants' implied warranties of merchantability and fitness.

82. The LiNA Medical Defendants breached the implied warranty of merchantability and fitness because the Xcise model power morcellator used in Plaintiff's hysterectomy was not fit for the ordinary purposes for which morcellators are used.

83. As a direct, foreseeable, and proximate result of the LiNA Medical Defendants' breaches of implied warranties, Plaintiff suffered damages.

(COUNT VI - NEGLIGENCE AGAINST LINA MEDICAL DEFENDANTS)

84. Plaintiff incorporates by reference herein all allegations set forth above.

85. The LiNA Medical Defendants owed a duty to Plaintiff to exercise ordinary care in the design, marketing, and sale of their Xcise model morcellator.

86. The LiNA Medical Defendants breached the duties owed to Plaintiff in the following particulars, among others:

(a) Failing to design their Xcise morcellator for safe use in hysterectomies;

(b) Failing to conduct adequate and appropriate testing of their Xcise morcellator;

(c) Failing to keep abreast of scientific literature and studies which provided the LiNA Medical Defendants notice of the risks associated with the use of laparoscopic power morcellators;

(d) Failing to appropriately respond to their own and others testing of, and information regarding laparoscopic power morcellators, which indicated such products' potential harm to humans;

(e) Failing to promptly disseminate new safety information and data regarding their products after their Xcise morcellator was released on the market;

(f) Failing to adequately warn of the actual potential for the dissemination and/or worsening of uterine cancer when using laparoscopic power morcellators for uterine morcellation;

(g) Failing to timely withdraw products used for uterine morcellation from the market, restrict their uses and adequately warn of such products' potential dangers.

87. The LiNA Medical Defendants knew or should have known that patients, including Plaintiff, would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as illustrated above.

88. Defendants' negligence caused Plaintiff to suffer damages.

(COUNT VII – VIOLATION OF WEST VIRGINIA CONSUMER CREDIT AND PROTECT ACT AGAINST LINA MEDICAL DEFENDANTS)

89. Plaintiff incorporates by reference herein all allegations set forth above.

90. Upon information and belief, the LiNA Medical Defendants, by the acts and misconduct alleged, violated the West Virginia Consumer Credit and Protection Act, *W.Va. Code* §46A-6-101, *et seq*.

91. Plaintiff is a "consumer" within the meaning of *W.Va. Code* §46A-6-102.

92. In violation of *W.Va. Code* §46A-6-101, *et seq.*, Defendant made untrue, deceptive or misleading representations of materials facts to, and omitted and/or concealed material facts from Plaintiff in marketing and advertising campaigns, among other ways, regarding the safety and use of its morcellator products. The unfair methods of competition and/or deceptive acts or practices are as follows:

(a) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services. W.Va. Code §46A-6-102(7)(B).

(b) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have […]. W.Va. Code §46A-6-102(7)(E).

(c) Engaging in any other conduct which similarly creates a likelihood of confusion or of misunderstanding. W.Va. Code §46A-6-102(7)(L).

(d) The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission, of any material fact with intent that others rely upon such concealment suppression or omission, in connection with the sale or advertisement of any goods or services, whether or not any person has in fact been misled, deceived or damaged thereby. W.Va. Code §46A-6-102(7)(M).

93. Defendants knew or should have known that the use of the Xcise model morcellator could cause the upstaging of uterine cancer in a significant subset of patients undergoing hysterectomies.

94. The misrepresentations and omissions described herein were likely to deceive Plaintiff and/or conceal the actual risks associated with Plaintiff's purchasing medical services involving the Xcise model morcellator.

95. Plaintiff, or her physicians and healthcare providers on her behalf, relied on the above misleading representations, failure to disclose, or both, to Plaintiff's detriment.

96. At all material times, Defendants actually knew of the defective nature of the Xcise model morcellator as set forth herein, and nevertheless continued to make false and/or

misleading promotions, representations, advertising, and statements regarding the Xcise model morcellator so as to maximize profits at the expense of public health and safety.

97. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have authorized and/or paid for the procedure involving the Xcise model morcellator (directly on through her surgeon and/or the health care facility at which her surgery was performed), and would not have incurred related medical costs and injury.

98. As a direct and proximate result of Defendants' conduct in violation of W.Va. Code §46A-6-101, *et seq*., Plaintiff suffered injuries and economic loss, entitling her to statutory and compensatory damages, including attorney fees.

(COUNT VIII – NEGLIGENT MISREPRESENTATION AGAINST LINA MEDICAL DEFENDANTS)

99. Plaintiff incorporates by reference herein all allegations set forth above.

100. The LiNA Medical Defendants represented that the Xcise model morcellator was as safe or safer, and as effective or more effective, than other surgical alternatives, and that the Xcise model morcellator offered additional benefits compared to surgical alternatives available on the market.

101. The LiNA Medical Defendants made these misrepresentations and actively concealed adverse information at a time when Defendants knew, or should have known, that the Xcise model morcellator had life-threatening defects and characteristics that were other than what Defendants represented to Plaintiff, her physicians, and/or health care providers.

102. The LiNA Medical Defendants negligently and/or intentionally misrepresented or omitted necessary and required information in the product labeling, promotions, and advertisements, and instead labeled, promoted, and advertised the Xcise model morcellator as

safe and more effective than other types of surgical alternatives and understated the product's life-threatening risks.

103. The foregoing misrepresentations were untrue and/or misleading.

104. The LiNA Medical Defendants knew or should have known that these representations were false and made the representations with the intent that Plaintiff and/or her physicians would rely on them.

105. As a direct and proximate result of the LiNA Medical Defendants' misrepresentations, suppression of information, and omissions, Plaintiff suffered damages.

(COUNT IX – FRAUDULENT CONCEALMENT AGAINST LINA MEDICAL DEFENDANTS)

106. Plaintiff incorporates by reference herein all allegations set forth above.

107. At all times during the course of dealings between the LiNA Medical Defendants and Plaintiff, and/or her healthcare providers, Defendants misrepresented the safety of the Xcise model morcellator for its intended use.

108. In representations to Plaintiff, and/or her healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

(a) That the Xcise model morcellator was not as safe or effective as other forms of uterine surgery;

(b) That Defendants failed to adequately investigate, research, study, and consider that occult cancerous cells would be disseminated by the their Xcise model morcellator;

(c) That Defendants failed to investigate, research, study and publish, in detail, the safety profile of the Xcise model morcellator;

(d) That Defendants failed to include an adequate warning about the life-threatening risks associated with the Xcise model morcellator's use in patients with occult cancer;

(e) That Defendants failed to adequately inform physicians and/or health care providers that for patients with occult cancer, the Xcise model morcellator would disseminate malignant cells throughout the patient's abdomen.

109. Defendants maintained a duty to disclose to Plaintiff, her physicians, healthcare providers, and/or hospitals the defective nature of the Xcise model morcellator, including, but not limited to, the life-threatening risks of disseminating malignant cells throughout the patient's abdominal cavity.

110. Plaintiff and her physicians, healthcare providers, and/or hospitals reasonably relied on facts which negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

111. As a result of the foregoing acts and omissions, Plaintiff suffered damages.

VII. Prayer for Relief

WHEREFORE, Plaintiff Mary Ann Ward, requests judgment against the United States of America, Raleigh General Hospital, LLC; LifePoint Health; and the LiNA Medical Defendants on each of the above-referenced claims as follows:

(a) Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to, damages for pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in amount to be determined at trial of this action;

(b) Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings, loss of household services and/or other economic damages in an amount to be determined at trial of this action;

(c) *Punitive and/or exemplary damages* for demonstrating conscious indifference and/or deliberate conduct so outrageous that malice can be implied to Plaintiff in an amount sufficient to punish each and every one of the Defendants and deter future similar conduct;

(d) Awarding reasonable attorneys' fees;

(e) Awarding Plaintiff the cost of these proceedings; and

(f) Such other and further relief as this Court deems just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY.

MARY ANN WARD, Plaintiff,
--By Counsel—

/s/ Robert M. Bastress III

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